Attorney Docket No.: 2003039-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kaern et al.	Art Unit:	3761
Serial No.:	10/579,770	Examiner:	Treyger
Filed:	3 December 2007	Conf. No.:	5690

Title: Device for Providing Anti-Reflux in a Body Fluid Collection and/or Sampling System, and Method of Manufacturing Such a Device

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MAIL STOP AF
Honorable Commissioner for Patents
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Via EFS-Web

Request for Pre-Appeal Brief Conference

This communication is in response to a Final Office Action mailed on July 14, 2009 and is being filed concurrently with a Notice of Appeal.

Remarks

Applicant relies upon the complete record before the Office to set forth the details of the application and the claimed invention. Further, Applicant's previous remarks made during prosecution are herein incorporated by reference.

Claim 1-12 and 14 – 19 are pending and all but claim 5 have been rejected under 35 USC 103(a). Claim 5 has been indicated allowable.

The primary issue that will be presented for Appeal is whether the rejection of the independent claims under 35 USC 103, over a single reference (Boedeker), which teaches a valve that *requires* securement holes for operation renders obvious a claim that (among other things) requires that the valve project a coherent plane which has been explicitly defined to mean that no material is stamped, punched or cut out, i.e., no material has been removed from within the outer contour of the valve; a definition acknowledged by the Examiner. In other words, the present claim(s) explicitly exclude what the reference requires.

The stated position in the Office Action is that the "omission of an element and its function is obvious if the element is not desired" and further that "if the holes are not desired and are not present, then the remaining elements will perform the same function."

Notably, this unsupported conclusion is factually incorrect.

The Office Action further states that "the hole can be removed together with its function." Again, this is an unsupported conclusion that is at odds with the teachings of the prior art.

Applicant notes that the embodiment relied for the rejection is described through slightly less that 1 ½ columns of text (Col. 2 line 46 – Col. 4 line 2). The vast majority of that description (almost an entire column) is provided to describe the holes (which the Examiner asserts are so easily omitted) and the retaining member 42 with pins that work with those holes along with the explicit reason why the hoes and mating pins are critical to the teachings of the reference (Col 3, line 3 – Col 4, line 2).

The reference teaches at Col. 3 line 47 that by spacing the valve element away from the connector, it is able to "float" and thereby remain functional through a sterilization process, wherein if it were sealed against the connector 26, the sterilization process would distort the

valve and render it inoperable. The ability to "float" is provided by the cooperation of the pins 46 through the holes 40 and the ability to space the rim 44 of the retaining member 42 *away* from the valve 36.

Accordingly, despite the unsupported statements to the contrary in the Office Action, elimination of the holes from the Boedecker device would not permit the remaining elements to continue to perform their same function; in fact, they could not perform the same function. The entire operation of the device for its intended purpose would be called into question, a fact explicitly stated in the reference.

> If the valve element is sealed to the connector, such sterilization may cause a distortion of the valve element and a malfunction of the anti-reflux mechanism during use. In contrast, according to the present invention, the valve element 34 of the anti-reflux device is permitted to float relative to the port 30 and the connector 26, in order that the valve element and connector may independently assume a different shape during the sterilization process without degrading the operation of the valve element in opening and closing the port. *Moreover, if the valve element is sealed to the connector, the valve element may become distorted during the sealing operation, such that the valve element may fail to function properly during use*." Col. 3, lines 47 – 60 (Emphasis Added).

In short, this teaching directly contradicts the Examiner's purported modification; particularly, as there is no objective evidence as to why such a modification would otherwise have been made in the first place. The only basis to make such a conclusion is the roadmap provided by Applicant's application and pending claims; which by definition, relies upon impermissible hindsight.

Removal of the holes would require modification of the Boedecker device to provide some other means of attachment. No such secondary reference has been provided. Further, omission of the holes would require that the valve be "sealed" against the connector since there would no longer be the ability to "float." This sealing attachment is explicitly taught away from by Boedecker.

The tenor of the Office Action is that the Bodecker valve (considered in the abstract) *could* be made to project a coherent plane; the holes in the valve (as taught) are elements; therefore their removal – or omission – would be obvious. This fails to consider the teachings of

the reference as a whole and fails to consider the claims as a whole. The mere assertion that a reference *could* be modified into something different, is not sufficient under the patent laws or rules of practice to establish a primae facie case of obviousness. There must be some objective evidence that teaches, suggests or otherwise supports a modification as proposed by the Examiner in the record in order to support such a showing.

The Bodecker holes are an *essential* element of the references; their removal is not akin to selecting among optional parts that have no bearing on the operability of the remaining structure (as is the situation with the case law cited in the form paragraphs). Thus, the holes are simply not a "nonessential" element that may be omitted based upon user preference or some other generic interest.

The need for such holes in the Boedekcer reference is explicit; they are required for proper operation of the valve. The function of the presently claimed valve having a coherent plane is also explicit; the manufacture of such a valve avoids generating waste pieces that can adversely affect valve performance. No reference or combination of references have been provided which teach these features.

Of course, the claims must be read as a whole and in their entirety. There are other elements in the claims and their interrelation with the valve having a coherent plane must also be properly construed and considered. Applicant has focused solely on the issue of whether the "omission" of the holes from the reference is proper, permissible, supported by the objective record and would render the claims obvious. As such, Applicant does not acquiesce any other arguments or issues which could have been presented.

Applicant respectfully asserts that the present claims are allowable over the art of record and requests a decision by the panel that is consistent with the conclusion.

Applicant has authorized the payment of the Notice of Appeal fee in the attached fee transmittal form. No other fees are believed due at this time, however, if this is in error, the office is authorized to charge or credit deposit account 50-4439.

Respectfully submitted,
Kaern et al.,

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